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10/065,892	11/27/2002	John Frederick Schenck	RD-29597	5293

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EXAMINER

CHAO, ELMER M

ART UNIT	PAPER NUMBER
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3737

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/065,892

Applicant(s)

SCHENCK ET AL.

Examiner

Elmer Chao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. Acknowledgement is made of Applicants' response filed 2/27/2007.

Response to Amendment

2. The amendment filed 2/27/2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Claims 1, 11, and 28 were amended to include the word "single". The support for this phrase is not supported by the originally filed documents and is considered new matter in the disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **Claims 1, 11, and 28** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1, 11, and 28 were amended to

include the word "single". The support for this phrase is not supported by the originally filed documents and is considered new matter in the disclosure. Also see the Response to Arguments section below.

Applicant is required to cancel the new matter in the reply to this Office Action.

Response to Arguments

5. The Examiner acknowledges Applicants' request to hold the double-patenting rejection in the Office Action dated 11/2/2006 in abeyance. However, until the Applicants file a terminal disclaimer, the double patenting rejection will be maintained.

6. Applicant's arguments filed 2/27/2007 have been fully considered but they are not persuasive.

7. With respect to Applicants' arguments regarding claims 1, 11, and 28, Applicants argue that the Bartzokis reference does not teach or suggest the recited steps of acquiring by a MRI system operating at a single substantially high magnetic field strength and thereafter analyzing the image data set for statistically relevant quantities of iron in order to indicate a given disease. However, in light of the specification, Examiner has determined that there is no language that supports the narrow limitation of the newly added phrase "a single substantially high magnetic field strength" in claims 1, 11, and 28. Examiner can only interpret the phrase "a single substantially high magnetic field strength" at most to mean "a substantially high magnetic field strength" as disclosed in the Specifications (Para [0005]; Para [0021]), and not as "only one

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substantially high magnetic field strength". Therefore, the Bartzokis reference does in fact read on claims 1, 11, and 28.

Moreover, even assuming Examiner interprets the phrase "a single substantially high magnetic field strength" to mean "only one substantially high magnetic field strength", the Bartzokis reference still teaches the recited steps as claimed in claims 1, 11, and 28. Bartzokis teaches acquiring a magnetic resonance images data set using a MRI system operating at only one substantially high magnetic field strength (col. 4, lines 11-17). With respect to Applicants' assertion that Bartzokis reference teaches taking MR images at two different field strengths instead of at a single field strength, according to col. 4, lines 11-30, Bartzokis actually teaches acquiring a *second* magnetic resonance images data set using a *second* MRI system operating at only one substantially high magnet field strength (*italics for emphasis*) (col. 4, lines 20-21, "...second magnetic resonance imaging instrument..."), in which case the Bartzokis reference would not be acquiring a data set using a MRI system operating at more than one magnetic field strength. Therefore, the claimed language, "acquiring a magnetic resonance (MR) images data set using a MRI system operating at a single substantially high magnetic field strength..." is still read on by the Bartzokis reference. Also see column 5, lines 57-69 for further support of how a complete data set is taken at only one magnetic field strength.

8. With respect to Applicants' arguments regarding claims 2-4, 7, 9-10, 12-14, 18, 20, 21, 23, 29, and 32-33, Applicants' attention is directed above to the discussion of claims 1, 11, and 28. For the reasons discussed above with respect to claims 1, 11,

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and 28, the rejection of claims 2-4, 7, 9-10, 12-14, 18, 20, 21, 23, 29, and 32-33 will be maintained over Bartzokis.

9. With respect to Applicants' arguments regarding claims 5, 15-17 and 24-27, Applicants argue that neither the Bartzokis nor the Sibbitt reference teaches analyzing the image data set in order to indicate a given disease. However, the Bartzokis reference does teach analyzing the image data set in order to indicate a given disease. Bartzokis teaches a second scan, differencing the two recorded scans, and storing the quantitative difference or displaying the quantitative difference as an image in order to map the relationship of ferritin concentrations to neurologic disorders and other disease states (see col. 5, line 57 – col. 6, line 7).

10. With respect to Applicants' arguments regarding claims 6, 8, 19, 22, 30, and 31, Applicants' attention is directed above to the discussion of claims 1, 11, and 28. For the reasons discussed above with respect to claims 1, 11, and 28, the rejection of claims 6, 8, 19, 22, 30, and 31 will be maintained over Bartzokis '682.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. **Claims 1, 6, 7, 11, 12, 15, 16, 19, 20, and 21** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, 7, 9, 10, 11, and 14 of copending Application No. 10/617543 (hereafter referenced as the '543 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '543 application claims a method and a system for using MRI to image brain iron deposits using a substantially high magnetic field strength including monitoring disease progression and response to therapy. Although the '543 does not explicitly claim volumetric measurements, a three dimensional phase image of the brain is created. An image processor, as claimed in the '543 application claim 9 for detecting iron deposits, serves as the computer analysis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. **Claims 1-4, 7, 9-14, 18, 20, 21, 23, 28, 29, and 32-33** are rejected under 35 U.S.C. 102(b) as being anticipated by Bartzokis et al. (U.S. 5,322,682). Bartzokis '682 discloses a magnetic resonance device and method used to measure iron stores in tissue (C1, L8-10) to aid in detection of disease (C1, L14-26; C6, L3-7). The method and system are used in diagnosis, prognosis, and monitoring treatment. The iron stores at each point within a region are quantified in the tissue based on the concentration of iron stores (C4, L31-36). MR images are acquired at a substantially high magnetic field strength of 1.5 Tesla (Abstract, "higher field strength"; Fig 2, "1.5 Tesla"; Fig 3, "1.5 Tesla") and are T₂- weighted (C2, L2) with substantially thin slices of 3mm (C9, L7). Bartzokis '682 additionally discloses that other sequences could be used, such as gradient echo sequences that quantify T₂ (C9, L8-10) and that any sequence that included a T₂ influence could be used. Dual spin-echo sequences were used to produce gray scale encoded T₂ maps (C9, L19-20; Fig 1). Enhancement of the image is done by computer-aided analysis using T₂ measurements as well as magnification and datagraphic corrections (C6, L46-68), which allow T₂ measurements to be derived from gray matter. Data is obtained from multiple subjects and analyzed to provide clinical population data which provides data for comparison of various regions of interest, such as white matter, caudate, putamen, and g. pallidus (Fig 3).

Assuming Examiner interprets the phrase "a single substantially high magnetic field strength" to mean "only one substantially high magnetic field strength", the Bartzokis reference still teaches the recited steps as claimed in claims 1, 11, and 28.

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Bartzokis teaches acquiring a magnetic resonance images data set using a MRI system operating at only one substantially high magnetic field strength (col. 4, lines 11-17).

With respect to Applicants' assertion that Bartzokis reference teaches taking MR images at two different field strengths instead of at a single field strength, according to col. 4, lines 11-30, Bartzokis actually teaches acquiring a *second* magnetic resonance images data set using a *second* MRI system operating at only one substantially high magnet field strength (italics for emphasis) (col. 4, lines 20-21, "...second magnetic resonance imaging instrument..."), in which case the Bartzokis reference would not be acquiring a data set using a MRI system operating at more than one magnetic field strength. Therefore, the claimed language, "acquiring a magnetic resonance (MR) images data set using a MRI system operating at a single substantially high magnetic field strength..." is still read on by the Bartzokis reference. Also see column 5, lines 57-69 for further support of how a complete data set is taken at only one magnetic field strength.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. **Claims 5, 15-17, 24-27** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartzokis '682 in view of Sibbitt et al (US 6,385,479 B1). Bartzokis

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'682, as discussed above, substantially discloses the invention as claimed, however fails to disclose the use of volumetric measurements. However, Sibbitt '479 discloses a method and system for determining central nervous system disease or injury using T2 measurements that are acquired at high magnetic field strengths (C4, L46-60). Digital information may be displayed as either two-dimensional or three-dimensional images (C4, L65-67). Segmentation is used to analyze the brain (C3, L30-33) to provide precise measures of T2 that are used to diagnose disease and disease activity (C7, L38-40). MR data may be proton density weighted or T2 weighted (C5, L1-5) to provide images. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Bartzokis '682 with the teachings of the reference by Sibbitt '479 in order to provide three dimensional volumetric images which may be analyzed by segmentation, as viewing the data in three dimensions provides additional diagnostic information which may be beneficial for use in monitoring a progressive disease.

17. **Claims 6, 8, 19, 22, 30, and 31** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartzokis '682. Bartzokis '682, as discussed above, substantially discloses the invention as claimed, however fails to explicitly disclose using the system to monitor Huntington's disease and Hallervorden Spatz disease. However, Bartzokis does disclose use for "various neurological disorders such as Alzheimer's and Parkinson's disease" (C1, L22-23). It would be an obvious modification to one of ordinary skill in the art to include both Huntington's disease and Hallervorden Spatz

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disease, as they are both degenerative brain disorders, wherein Hallervorden Spatz disease also includes brain iron accumulation. Additionally, Bartzokis fails to disclose use of slice thickness of 1.5mm or less, however does explicitly disclose use of thin slices of 3mm. It would be an obvious modification to one of ordinary skill in the art to reduce the slice thickness in order to provide more data for analysis, as previously discussed.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elmer Chao whose telephone number is (571)272-0674. The examiner can normally be reached on 9am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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